

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/607,745	DARROW ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sheridan L. Swope	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Election of August 18, 2003.
2. ☒ The allowed claim(s) is/are 16-18 and 25.
3. ☒ The drawings filed on 30 June 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                       | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.            |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. <u>0803</u> | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                 | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|   | 9 <input type="checkbox"/> Other _____.   |

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### **DETAILED ACTION**

Applicant's election without traverse of Invention IV, Claims 16-18 in the paper received August 18, 2003 is acknowledged. It is acknowledged that applicant's have cancelled Claims 1-16 and 19-23 and added Claims 24 and 25. Claims 16-18, 24, and 25 are pending. Claims 24 and 25 are deemed to be within the elected invention. Claims 16-18, 24, and 25 are hereby examined on their merits.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

For the Claims:

1 - 15 (canceled).

16 (currently amended).      A method to detect test compound modulation of proteolytic activity comprising the steps:

a) incubating a test compound, the proteolytically active protease of SEQ ID NO: 2, and a labeled substrate for sufficient time to produce a detectable product as a result of proteolytic activity upon the labeled substrate; and

b) measuring a change in the quantity of product as a result of test compound modulation of said protease activity on the labeled substrate, when compared to protease activity on the labeled substrate in the absence of test compound.

17 (previously presented).      The method of claim 16 wherein the labeled substrate

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comprises a detectable label selected from the group consisting of a radiolabeled atom, at least one fluorescent molecule, and a colorimetric molecule.

18 (original). The method of claim 17 wherein the substrate is labeled with two fluorescent molecules, and the detectable molecule is detected by fluorescent resonant energy transfer.

19-24 (canceled).

25 (amended). A method to detect test compound modulation of proteolytic activity comprising the steps:

a) incubating a test compound, a proteolytically active fusion as set forth by SEQ ID NO: 9, and a labeled substrate for sufficient time to produce a detectable product as a result of proteolytic activity upon the labeled substrate; and

b) measuring a change in the quantity of product as a result of test compound modulation of said protease activity on the labeled substrate, when compared to protease activity on the labeled substrate in the absence of test compound.

Authorization for this examiner's amendment was given in a telephone interview with Linda Evans on December 4, 2003.

***Allowable Subject Matter***

Claims 16-18 and 25 are allowed.

The following is an examiner's statement of reasons for allowance:

All elected Claims, 16-18 and 25, are limited to methods for detecting test compound modulation of the proteolytic activity of the protease of SEQ ID NO: 2 or the catalytic domain thereof in a fusion protein, SEQ ID NO: 9.

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The utility of said method, detecting test compound modulation of the proteolytic activity of the protease of SEQ ID NO: 2, is credible based on expression in heterologous host cells and analysis by an enzymatic assay using a variety of synthetic substrates (Table 1). Testing the effect of a test compound to modulate said proteolytic activity could be accomplished by adding the test compound to the reactions described by Table 1. Such techniques are standard in the art; however, the claimed methods would not have been obvious to a person of ordinary skill in the art to one of skill in the art as the prior art fails to teach or suggest a protease of SEQ ID NO: 2 or 9.

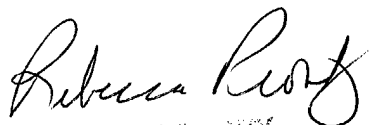
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph. D.



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